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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JANSSEN BIOTECH, INC. Plaintiff, v. SAMSUNG BIOEPIS, CO., LTD. Defendant.	)	Civil Action No. 2:17-cv-03524 (MCA) (SCM) **ANSWER AND DEFENSES OF DEFENDANT SAMSUNG BIOEPIS CO., LTD.**

Defendant Samsung Bioepis Co., Ltd. ("Defendant"), by its attorneys, hereby answers the Complaint of Janssen Biotech, Inc. ("Plaintiff") as set forth below. In addition to the answers, objections, and denials set forth, Defendant also denies each of the allegations contained in the headings used by Plaintiff. Further, and as noted elsewhere herein, Defendant objects to Janssen's continued maintenance of allegations and claims relating to alleged violations of the BPCIA based on legal arguments which have been rejected by the U.S. Supreme Court in *Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). Although Defendant has inquired of Plaintiff as to Plaintiff's filing of an amended pleading, Plaintiff has not done so, thereby requiring Defendant to unnecessarily respond to flawed claims.

NATURE OF THE ACTION

1. This is an action for patent infringement under 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 in the part of the Patient Protection and Affordable Care Act known as the Biologics Price Competition and Innovation Act ("BPCIA").

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant admits that Plaintiff's Complaint purports to recite a civil action for patent infringement and, in particular, under 35 U.S.C. § 271(e)(2)(C). Defendant denies the remaining allegations in paragraph 1 of the Complaint.

2. This is also an action to enforce the patent dispute resolution provisions of the BPCIA, which Bioepis has refused to follow to date.

ANSWER: Defendant denies the allegations of paragraph 2 and denies that Plaintiff is entitled to any relief in this action. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017).

3. The BPCIA created an abbreviated regulatory pathway for the approval of biosimilar versions of biological medicines. The BPCIA pathway allows biosimilars makers to avoid the full complement of pre-clinical and clinical studies required for regulatory approval and instead rely on data supporting the safety and efficacy of the innovative biological product which the biosimilar mimics. By taking advantage of the BPCIA regulatory pathway, biosimilars makers can greatly reduce the time and expense of obtaining marketing approval.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 3.

4. In order to prevent the new biosimilar pathway from undermining the intellectual property rights of innovators and thereby deterring innovation, the BPCIA also created an intricate and carefully orchestrated set of dispute resolution procedures to facilitate the orderly resolution of patent disputes before a biosimilar product could enter the market.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 4 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 4.

5. Pursuant to the BPCIA, Bioepis submitted an abbreviated Biologic License Application ("aBLA") seeking permission to market a proposed biosimilar version of Janssen's revolutionary biological medicine Remicade® (infliximab).

ANSWER: Defendant admits that pursuant to the BPCIA, Samsung Bioepis submitted a Biologic License Application ("BLA") seeking FDA approval to market a proposed biosimilar to Remicade® (infliximab). Defendant denies the remaining allegations of paragraph 5.

6. Bioepis's aBLA was accepted for review by the Food and Drug Administration ("FDA") on May 20, 2016.

ANSWER: Defendant admits that Bioepis's BLA was accepted for review by the Food and Drug Administration ("FDA") on May 20, 2016.

7. The FDA approved Bioepis's aBLA on April 21, 2017.

ANSWER: Defendant admits that the FDA approved Bioepis's BLA on April 21, 2017.

8. The BPCIA's dispute resolution procedure involves a series of information exchanges and good-faith negotiations between the parties before the filing of a patent infringement lawsuit. Bioepis, however, has refused to follow these procedures.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 8 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and the allegations, of paragraph 8.

9. Despite making use of the BPCIA's abbreviated regulatory pathway and Janssen's research and development leading to the approval of Remicade®, Bioepis short-circuited the

BPCIA's patent dispute resolution process by withholding the information necessary for Janssen to assess infringement. The U.S. Supreme Court is currently evaluating whether a biosimilar maker may lawfully make use of the BPCIA's regulatory pathway while failing to provide its aBLA and manufacturing information to the innovator company so as to allow the innovator company to assess infringement.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 9 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 9. Defendant denies that its action or inaction was in violation of the BPCIA as interpreted by the U.S. Supreme Court.

10. Bioepis further thwarted the BPCIA patent dispute resolution process by serving what it denominated a "notice of commercial marketing" well in advance of when it was allowed to do so by law. Under applicable law, a biosimilar applicant cannot serve its notice until after the FDA approves the aBLA, resulting in a licensed biosimilar product.

ANSWER: Defendant denies the allegations of paragraph 10 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). Defendant denies that its action or inaction was in violation of the BPCIA as interpreted by the U.S. Supreme Court.

11. Bioepis has indicated that it will comply with applicable law but has not withdrawn its premature, purported "notice of commercial marketing." Bioepis also served a proper notice of commercial marketing on April 21, 2017, upon FDA approval of its aBLA, in

accordance with applicable law. The issue of whether a notice of commercial marketing must be provided after licensing under the BPCIA, as the Court of Appeals for the Federal Circuit has held, is currently before the U.S. Supreme Court.

ANSWER: Defendant denies all characterizations of the law, including statutes and pertinent case law. Defendant denies the allegations of paragraph 11 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). Defendant denies that Bioepis' notice of commercial marketing served on May 26, 2016 was premature. Defendant denies the remaining allegations of paragraph 11. Defendant denies that its action or inaction was in violation of the BPCIA as interpreted by the U.S. Supreme Court.

12. In light of Bioepis's actions as well as the issues before the U.S. Supreme Court, Janssen is asserting, in addition to its claims for violations of the BPCIA, claims for infringement of three patents under 35 U.S.C. § 271(e)(2)(C)(ii) based on Bioepis's submission of the aBLA and its failure to provide its aBLA and manufacturing information to Janssen as set forth under the BPCIA.

ANSWER: Defendant admits that Plaintiff's Complaint purports to assert claims for infringement of three patents under 35 U.S.C. § 271(e)(2)(C)(ii) based on Bioepis's submission of its BLA. Defendant denies the allegations of paragraph 12 as a misstatement of applicable law. Defendant denies that Plaintiff has stated a claim upon which relief can be granted based on Plaintiff's claims for alleged violations of the BPCIA due to Bioepis's alleged failure to provide manufacturing information to Plaintiff in addition to the BLA itself. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). Defendant denies the remaining allegations of paragraph 12. Defendant denies that its action or inaction was in violation of the BPCIA as interpreted by the U.S. Supreme Court.

PARTIES

13. Janssen Biotech, Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business in Horsham, Pennsylvania.

ANSWER: Defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 13, and therefore denies same.

14. On information and belief, Samsung Bioepis Co., Ltd. is a company organized and existing under the laws of the Republic of Korea. Samsung Bioepis Co., Ltd. is a biopharmaceutical company that specializes in research and development of biosimilars and biopharmaceuticals. Samsung Bioepis Co., Ltd. markets and distributes such biopharmaceutical products in the United Sates, including through its distributor and commercialization partner Merck & Co., Inc.

ANSWER: Defendant admits that Samsung Bioepis Co., Ltd. is a company organized and existing under the laws of the Republic of Korea. Samsung Bioepis Co., Ltd. is a biopharmaceutical company that specializes in research and development of biosimilars and biopharmaceuticals. Defendant admits that its U.S. distributor is Merck & Co., Inc. Defendant denies that Samsung Bioepis Co., Ltd. markets and distributes such biopharmaceutical products in the United Sates. Defendant denies the remaining allegations of paragraph 14.

JURISDICTION AND VENUE

15. This is an action for violations of 42 U.S.C. § 262(*l*), and patent infringement under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

ANSWER: Defendant admits that the Complaint purports to bring a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code.

Defendant denies that Plaintiff has stated a justiciable claim for violation of 42 U.S.C. § 262(*l*) and denies that the BPCIA provides for a private right of action to enforce alleged violations of 42 U.S.C. § 262(*l*). Defendant denies that Plaintiff is entitled to any relief in this action. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). The remaining allegations of paragraph 15 contain legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 15.

16. On information and belief, Bioepis has been approved to market and distribute its proposed biosimilar infliximab product throughout the United States, including in New Jersey.

ANSWER: Defendant admits that Bioepis has been approved to market and distribute its proposed biosimilar product throughout the United States, including the State of New Jersey.

17. On information and belief, Bioepis has entered into a development and commercialization agreement with Merck & Co., Inc. ("Merck") to market and distribute its biosimilar infliximab product in New Jersey. Merck is headquartered in New Jersey.

ANSWER: Defendant admits that Bioepis and Merck have entered into an agreement relating to the potential marketing and distribution of Bioepis's proposed biosimilar infliximab product in the United States. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 17 and, therefore, denies same.

18. On information and belief, and as Bioepis has asserted, Bioepis intends to "engage in the commercial manufacture, use, and/or sale" of its biosimilar infliximab product, which will be purposefully directed at New Jersey and throughout the United States.

ANSWER: Defendant admits that Bioepis intends to "engage in the commercial manufacture, use, and/or sale" of its biosimilar infliximab product in the United States, which

may include the State of New Jersey. Defendant denies the remaining allegations of paragraph 18.

19. On information and belief, and as Bioepis has asserted, Bioepis intends to engage in the commercial manufacture, use, or sale of its biosimilar infliximab product before the expiration of Janssen's patents throughout the United States, including in New Jersey. Indeed, Bioepis has been approved to engage in such commercial manufacture, use and sale.

ANSWER: Defendant admits that Bioepis intends to engage in the commercial manufacture, use, or sale of its biosimilar infliximab product before the expiration of Janssen's patents in the United States, which may include the State of New Jersey. Defendant admits that Bioepis has been approved to engage in such commercial manufacture, use and sale of its biosimilar infliximab product. Defendant denies the remaining allegations of paragraph 19.

20. On information and belief, Bioepis's development and commercialization agreement with Merck indicates that Bioepis plans to market its proposed biosimilar infliximab in New Jersey. Whether or not Bioepis itself intends to sell its biosimilar infliximab directly into New Jersey, it has a distributor with which it contracts to market its biosimilar infliximab in New Jersey.

ANSWER: Defendant admits that Bioepis intends to engage in the commercial sale of its biosimilar infliximab product in the United States, which may include the State of New Jersey. Defendant denies the remaining allegations of paragraph 20.

21. Bioepis's intended sales of its biosimilar infliximab before the expiration of Janssen's patents would irreparably injure Janssen in New Jersey by, among other things, displacing its New Jersey sales.

ANSWER: Defendant denies the allegations of paragraph 21.

22. Bioepis's submission of its aBLA to the FDA evinces its intent to subject itself to the jurisdiction of the courts where the drug that is the subject of the aBLA will be sold, including New Jersey.

ANSWER: Defendant denies the allegations of paragraph 22.

23. This Court's exercise of personal jurisdiction over Bioepis is fair and reasonable. Bioepis is not burdened by litigating this suit in New Jersey. New Jersey has an interest in providing a forum to resolve BPCIA litigation, including this case, because this litigation involves products that will be sold in New Jersey by a New Jersey-based company and injury to Janssen in New Jersey. This Court's exercise of jurisdiction serves the interests of Janssen and the judicial system in efficient resolution of litigation.

ANSWER: Defendant denies the allegations of paragraph 23. Defendant does not object to personal jurisdiction in New Jersey for the purpose of this civil action.

24. In the alternative, this Court's exercise of personal jurisdiction over Bioepis is also proper pursuant to Federal Rule of Civil Procedure 4.

ANSWER: Defendant denies the allegations of paragraph 24. Defendant does not object to personal jurisdiction in New Jersey for the purpose of this civil action.

25. Under Rule 4(k)(2), for a claim arising under federal law, jurisdiction in any federal court is proper where a defendant is (1) not subject to general jurisdiction in any state and (2) exercise of jurisdiction is consistent with the United States Constitution and laws.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant does not object to personal jurisdiction in New Jersey for the purpose of this civil action.

26. Bioepis has availed itself of the laws of the United States by, among other things, seeking and receiving approval for its biosimilar.

ANSWER: Defendant denies the allegations of paragraph 26. Defendant does not object to personal jurisdiction in New Jersey for the purpose of this civil action.

27. Litigating in the District of New Jersey would not burden Bioepis unduly. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Janssen has a substantial interest in obtaining convenient and effective relief for violations of its property interests. And the states also have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

ANSWER: Defendant denies the allegations of paragraph 27. Defendant does not object to personal jurisdiction in New Jersey for the purpose of this civil action.

28. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and/or 1400(b).

ANSWER: Defendant will not contest that venue is proper in this judicial district for this action, but otherwise denies the allegations of paragraph 28.

REMICADE® (INFLIXIMAB)

29. Janssen is a pioneer and leader in the development of biologic drugs. Janssen's biologic drug Remicade® was one of the first drugs of its kind sold in the United States for treatment of chronic disease.

ANSWER: Defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 29, and therefore denies same.

30. Remicade® is a monoclonal antibody that binds to and neutralizes a substance in our bodies called TNFα. TNFα is an important player in our immune systems but, if it is over-produced, it can cause chronic disease.

ANSWER: Defendant admits that infliximab (Remicade®) is a monoclonal antibody that binds to and neutralizes a substance in the human body called TNFα. Defendant admits that TNFα, if overproduced, can cause chronic disease. Defendant is without sufficient knowledge or information to admit or deny the remaining allegations in paragraph 30, and therefore denies same.

31. Although the antibody had promising in vitro properties, given its complex structure and mechanism of operation it required extensive pre-clinical and clinical development before it could become a useful medicine for human beings.

ANSWER: Defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 31, and therefore denies same.

32. From the time the infliximab antibody was first discovered, it took nearly a decade for Remicade® to be approved for sale in the United States. During that time, Janssen's predecessor Centocor conducted dozens of clinical trials and spent tens of millions of dollars, with no guarantee of success.

ANSWER: Defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 32, and therefore denies same.

33. Remicade® was first approved for the U.S. market in 1998. The first indication, or use, for which Remicade® was approved was the treatment of Crohn's disease, an inflammatory bowel disease that causes inflammation of the lining of the digestive tract. Remicade® was the first biological therapy approved for Crohn's disease in the United States.

ANSWER: Defendant admits that Remicade® was first approved for the U.S. market in 1998. Defendant admits that the first indication, or use, for which Remicade® was approved was the treatment of Crohn's disease, an inflammatory bowel disease of the digestive tract. Defendant is without sufficient knowledge or information to admit or deny the remaining allegations in paragraph 33, and therefore denies same.

34. After Remicade® entered the market, Centocor continued to pursue extensive clinical development efforts for the drug. These efforts led to the discovery that Remicade® is safe and effective for a number of additional diseases and indications other than Crohn's disease.

ANSWER: Defendant admits that Remicade® has been approved by the FDA for diseases and indications other than Crohn's disease. Defendant is without sufficient knowledge or information to admit or deny the remaining allegations in paragraph 34, and therefore denies same.

35. Janssen's extensive development efforts have led to 16 FDA approvals for Remicade®, including indications for use in the treatment of Crohn's disease (1998), rheumatoid arthritis (1999), ankylosing spondylitis, a chronic inflammatory disease of the axial skeleton (2004), psoriatic arthritis (2005), and ulcerative colitis, an inflammatory bowel disease (2006). Remicade® has changed the standard of care for the treatment of these diseases.

ANSWER: Defendant admits that Remicade® has been approved for use in the treatment of Crohn's disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis. Defendant is without sufficient knowledge or information to admit or deny the remaining allegations in paragraph 35, and therefore denies same.

36. In total, Janssen has sponsored more than 170 clinical trials for Remicade®. Janssen has spent hundreds of millions of dollars in research and development of the drug.

ANSWER: Defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 36, and therefore denies same.

37. Remicade® had been used to treat and improve the lives of more than 2.2 million patients suffering from chronic disease.

ANSWER: Defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 37, and therefore denies same.

JANSSEN'S CELL CULTURE MEDIA AND PURIFICATION PATENTS

38. Janssen asserts three of its patents for growing and purifying biologics, including infliximab, in this action.

ANSWER: Defendant admits that the Complaint purports to bring a civil action for patent infringement of three patents that Plaintiffs allege relate to growing and purifying biologics. Defendant is without sufficient knowledge or information to admit or deny the remaining allegations in paragraph 38, and therefore denies same.

The Chemical Cell Growth Media Patents (the '083 Patent and the '056 Patent)

39. On October 6, 2009, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,598,083 (the "'083 patent"), entitled "Chemically Defined Media Compositions." A true and correct copy of the '083 patent is attached as Exhibit A.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant admits that U.S. Patent No. 7,598,083 ("the '083 patent") is entitled "Chemically Defined Media Compositions." Defendant further admits that, according to its face, the '083 patent issued on October 6, 2009. Defendant admits that Exhibit A purports to be a copy of the '083 patent. Defendant denies the remaining allegations in paragraph 39.

40. On May 31, 2005, the PTO issued U.S. Patent No. 6,900,056 (the "'056 patent"), entitled "Chemically Defined Medium for Cultured Mammalian Cells." A true and correct copy of the '056 patent is attached as Exhibit B.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant admits that U.S. Patent No. 6,900,056 ("the '056 patent") is entitled "Chemically Defined Medium for Cultured Mammalian Cells." Defendant further admits that, according to its face, the '056 patent issued on May 31, 2005. Defendant admits that Exhibit B purports to be a copy of the '056 patent. Defendant denies the remaining allegations in paragraph 40.

41. Janssen owns the '083 and '056 patents, which cover cell growth media for use in growing biological products, including infliximab.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 41, and therefore denies same.

42. The '083 patent will expire on February 7, 2027.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 42, and therefore denies same.

43. The '056 patent will expire on October 5, 2022.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, defendant is

without sufficient knowledge or information to admit or deny the allegations in paragraph 43, and therefore denies same.

The Purification Patent (the '600 patent)

44. On August 10, 2004, the PTO issued U.S. Patent no. 6,773,600 (the "'600 patent"), entitled "Use of Clathrate Modifier, To Promote Passage of Proteins During Nanofiltration." A true and correct copy of the '600 patent is attached as Exhibit C.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant admits that U.S. Patent No. 6,773,600 ("the '600 patent") is entitled "Use of Clathrate Modifier, To Promote Passage of Proteins During Nanofiltration." Defendant further admits that, according to its face, the '600 patent issued on August 10, 2004. Defendant admits that Exhibit C purports to be a copy of the '600 patent. Defendant denies the remaining allegations in paragraph 44.

45. Janssen owns the '600 patent, which covers novel methods of purifying biological products such as infliximab so that they are suitable for use in human medicines.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 45, and therefore denies same.

46. The '600 patent will expire on June 4, 2023.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, defendant is

without sufficient knowledge or information to admit or deny the allegations in paragraph 46, and therefore denies same.

BIOLOGICS, BIOSIMILARS, AND THE BPCIA

Biologics

47. Biological medicines, or biologics, are complex biological molecules that need to be grown in living cultures rather than chemically synthesized, as are the more familiar pharmaceutical products known as chemical or small-molecule drugs. Because the biologic manufacturing process is complex and uses living organisms, the structural features of a biologic drug can vary based on the precise manner in which the drug is made. Unlike small-molecule drugs, moreover, biological molecules generally cannot be completely characterized.

ANSWER: Defendant is without sufficient knowledge or information to admit or deny the allegations in paragraph 47, and therefore denies same.

48. Because of the differences between biological and small-molecule drugs, biological and small-molecule pharmaceutical products are approved for sale in the United States through different regulatory pathways. Whereas small-molecule drugs are approved based on the submission of a New Drug Application ("NDA") *(see* 21 U.S.C. § 355), biological products are assessed pursuant to a Biological License Application ("BLA") *(see* 42 U.S.C. § 262(a)).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 48.

The BPCIA Pathway for Biosimilar Approval

49. Although Congress created an abbreviated regulatory pathway for the approval of generic small-molecule drugs in the Hatch-Waxman Act of 1984, no abbreviated pathway for approval of follow-on biologics products existed until the enactment of the BPCIA, as part of the Patient Protection and Affordable Care Act, in 2010. Before the enactment of the BPCIA, the only way to obtain U.S. approval of a biological product was through an original BLA supported by a full complement of pre-clinical and clinical data.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 49.

50. The BPCIA creates an abbreviated approval pathway for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). The BPCIA defines a "biosimilar" as a biological product that is (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (2) has "no clinically meaningful differences" with "the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(i)(2)(A), (B). The BPCIA defines a "reference product" to be a "single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant

denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 50.

51. Under the BPCIA, biosimilar applicants are permitted to make use of FDA's prior determinations as to the safety, purity, and potency of a reference product that was already approved by FDA. In particular, a biosimilar applicant must identify a single reference product that has already been approved by FDA and submit to FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I). Consequently, the § 262(k) pathway created by the BPCIA allows the biosimilar applicant to reduce the time, expense, and risks of research and development, avoid the full complement of pre-clinical and clinical testing required for an original product, and gain licensure to commercialize its biological product in the market as a biosimilar sooner and more cheaply than it could have done through the submission of an original BLA.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 51.

The BPCIA's Patent Dispute Resolution Procedures

52. As Congress expressly indicated, the purpose of the BPCIA is to establish "a biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant

denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 52.

53. To further this goal, Congress created a set of procedures for addressing patent disputes relating to prospective biosimilar drugs. These procedures are set forth in 42 U.S.C. § 262(*l*) and in corresponding amendments to the patent infringement statute, 35 U.S.C. § 271. The procedures are intended to ensure that the maker of an innovative biological product that is the subject of a biosimilar application will have sufficient time and opportunity to enforce its patent rights before a biosimilar product enters the United States market. The BPCIA's patent dispute resolution procedures are also intended to ensure that disputes over patent rights will take place in an orderly fashion, with the least possible uncertainty, brinksmanship, and burden on the parties and the courts.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 53 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 53.

54. The BPCIA patent dispute resolution procedures set forth a series of specific steps before any patent action is filed.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 54 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 54.

55. The BPCIA dispute resolution process begins when a biosimilar application is accepted for review by FDA. Within twenty days thereafter, the biosimilar applicant "shall provide" the reference sponsor with confidential access to "a copy of the application submitted ... under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). This step initiates a series of pre-litigation exchanges of information and positions so that the parties are able to engage in good-faith negotiations regarding what patents should be litigated prior to the approval of the biosimilar product. *See* 42 U.S.C. § 262(*l*)(2)-(*l*)(6).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 55 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 55.

56. The BPCIA's requirement that manufacturing information be provided reflects the complexity of manufacturing processes for biologics and their importance to innovation in the field. To ensure that full application and manufacturing information be made available without prejudice or delay, the BPCIA sets forth a detailed set of confidential access provisions governing the reference product sponsor's use of the required information. 42 U.S.C. § 262(*l*)(1).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 56 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 56.

57. The next step in the statutory process is 42 U.S.C. § 262(*l*)(3)(A). This section provides that within 60 days after receiving the information set forth in section 262(*l*)(2), the reference product sponsor "shall provide" the biosimilar applicant a list of patents for which the reference product sponsor "believes a claim of patent infringement could reasonably be asserted" against the proposed biosimilar product or the uses or manufacture of such product. 42 U.S.C. § 262(*l*)(3)(A)(i). The reference product sponsor also states whether it is willing to license any of these patents. 42 U.S.C. § 262(*l*)(3)(A)(ii).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 57 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 57.

58. The next statutory provision, section 262(*l*)(3)(B), states that within 60 days the biosimilar applicant "shall provide" a "detailed statement" of its non-infringement, invalidity, and unenforceability defenses with respect to the listed patents, or a statement that the applicant "does not intend to bring commercial marketing of the biological product before the date that such patent expires." 42 U.S.C. § 262(*l*)(3)(B)(ii).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 58 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 58.

59. The next statutory provision, section 262(*l*)(3)(C), states that within 60 days the reference product sponsor "shall provide" a "detailed statement" of its infringement positions and "a response to the statement concerning validity and enforceability provided" by the biosimilar applicant. 42 U.S.C. § 262(*l*)(3)(C).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 59 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 59.

60. After the exchange of detailed statements, the statute provides that the parties "shall engage in good faith negotiations" to agree on patents that will be subject to an action for patent infringement prior to the approval of the biosimilar application. 42 U.S.C. § 262(*l*)(4)(A).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 60 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 60.

61. If the parties agree on the patents that will be subject to an immediate action for infringement, then the reference product sponsor "shall bring an action for patent infringement" within thirty days of the agreement. 42 U.S.C. § 262(*l*)(6)(A). If the parties fail to reach agreement, they proceed to a further exchange process that will identify one or more patents for immediate litigation. 42 U.S.C. § 262(*l*)(4)(B) & (*l*)(5). As in the case of agreement, the

reference product sponsor "shall bring an action for patent infringement" within thirty days after patents are selected for litigation through this process. 42 U.S.C. § 262(*l*)(6)(B).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 61 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 61.

Notice of Commercial Marketing

62. In addition to the pre-litigation procedures described above, the BPCIA addresses litigation regarding a "biological product licensed under subsection (k)"-*i.e.*, a biosimilar product that has been approved for marketing. The BPCIA requires the biosimilar maker to provide "notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 62 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 62.

63. Upon receipt of a notice of commercial marketing, the reference product sponsor may move for a preliminary injunction on patents that the sponsor identified as potentially infringed under section 262(*l*)(3)(A) of the pre-litigation dispute resolution procedures, but

which the parties have not selected for litigation pursuant to these procedures. 42 U.S.C. § 262(*1*)(8)(B).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 63 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 63.

64. In addition, the notice of commercial marketing permits the reference product sponsor to bring a declaratory judgment action with respect to such patents that have been identified but not selected for immediate litigation. 42 U.S.C. § 262(*1*)(9)(A). Before the notice of commercial marketing, such declaratory judgments are prohibited. *Id.*

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 64 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 64.

BIOEPIS'S BIOSIMILAR PRODUCT

65. On information and belief, Bioepis has undertaken the development of a biosimilar to Janssen's Remicade® infliximab product.

ANSWER: Defendant admits that Bioepis has filed a BLA for a biosimilar to the Remicade® infliximab product. Defendant denies the remaining allegations of paragraph 65.

66. On information and belief, in 2013, Bioepis entered into an agreement with Merck pursuant to which Merck obtained the rights to market biosimilar infliximab in the United States.

The proposed biosimilar infliximab product to be marketed by Bioepis is referred to as SB2 or Renflexis®. It is also marketed in Europe as Flixabi®.

ANSWER: Defendant admits that Bioepis and Merck have entered into an agreement relating to potential marketing and distribution of Bioepis's proposed biosimilar to infliximab in the United States. Defendant admits that Bioepis's proposed biosimilar infliximab product is referred to as SB2 or Renflexis® in the United States and in Europe as Flixabi®. Defendant denies the remaining allegations of paragraph 66.

67. On information and belief, the FDA accepted Bioepis's aBLA for this proposed biosimilar product on or about May 20, 2016.

ANSWER: Defendant admits that Bioepis's BLA for its biosimilar to infliximab was accepted for review by the Food and Drug Administration ("FDA") on May 20, 2016.

68. On information and belief, the FDA approved Bioepis's proposed biosimilar product on April 21, 2017, for Crohn's disease, pediatric Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.

ANSWER: Defendant admits that the FDA approved Bioepis's BLA for Bioepis's biosimilar to infliximab on April 21, 2017, for the indications stated in the label. Defendant denies the remaining allegations of paragraph 68.

BIOEPIS'S EFFORTS TO AVOID
THE BPCIA'S PATENT DISPUTE RESOLUTION PROCEDURES

69. From the time it began the process of seeking approval for its proposed biosimilar product, Bioepis has sought to avoid the mandatory patent dispute resolution procedures of the BPCIA. Bioepis has elected to short-circuit the statutory process by withholding its aBLA and manufacturing information, by refusing to participate to date in subsequent statutory procedures, and by serving a premature "notice of commercial marketing."

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 69 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 69.

70. As set forth above, the BPCIA's dispute resolution procedures are triggered by FDA's acceptance of a biosimilar application for review. 42 U.S.C. § 262(*1*)(2)(A).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 70 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 70.

71. After the FDA accepted Bioepis's application for review on May 20, 2016, it sent Janssen a letter dated May 26, 2016, attached as Exhibit D.

ANSWER: Defendant admits that, after the FDA accepted Bioepis's application for review on May 20, 2016, in view of pending petitions for certiorari to the U.S. Supreme Court, Bioepis sent Janssen a letter dated May 26, 2016. Defendant admits that Exhibit D purports to be a copy of the letter dated May 26, 2016.

72. In its letter, Bioepis notified Janssen that its application had been accepted by the FDA for review pursuant to the BPCIA.

ANSWER: Defendant admits that Bioepis notified Janssen that its application had been accepted by the FDA for review pursuant to the BPCIA in the letter dated May 26, 2016.

73. Bioepis wrote that it was refusing to comply with the BPCIA's exchange information procedures, stating that it would "not provide Janssen Biotech, Inc. with a copy of BLA No. 761054 or any information that describes the process or processes used to manufacture the biological product that is the subject of BLA No. 761054."

ANSWER: Defendant admits that the letter dated May 26, 2016 states that "Bioepis will not provide Janssen Biotech, Inc. with a copy of BLA No. 761054 or any information that describes the process or processes used to manufacture the biological product that is the subject of BLA No. 761054." The remaining allegations of this paragraph contain legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 73 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law. Defendant denies the remaining allegations of paragraph 73.

74. Bioepis invited Janssen to bring suit against it on any patent that "claims the biological product or its use or its manufacture" while withholding all information necessary to evaluate infringement.

ANSWER: Defendant denies the allegations of paragraph 74. Defendant also denies the allegations of paragraph 74 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017).

75. Lastly, though Bioepis's product had not been approved by the FDA, Bioepis's May 26, 2016 letter purported to provide notice that it would "commence commercial marketing ... as soon as possible under applicable law after the FDA's approval to do so but no earlier than 180 days from receipt of this notice by Janssen Biotech, Inc."

ANSWER: Defendant admits that the letter dated May 26, 2016 states that "Bioepis will commence commercial marketing of the biological product that is the subject of BLA No. 761054 as soon as possible under applicable law after the FDA's approval to do so but no earlier than 180 days from receipt of this notice by Janssen Biotech, Inc." The remaining allegations of this paragraph contain legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 75 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137, S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law. Defendant denies the remaining allegations of paragraph 75.

76. On January 12, 2017, Janssen asked Bioepis to commit not to commercially market its proposed biosimilar until 180 days after FDA approval, as required by law.

ANSWER: Defendant admits that it received a letter from Janssen dated January 12, 2017, but otherwise denies the allegations of paragraph 76. Defendant denies the allegations of paragraph 76 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017).

77. Bioepis responded by letter of January 22, 2017, attached as Exhibit E.

ANSWER: Defendant admits that Bioepis responded by a letter dated January 22, 2017. Defendant admits that Exhibit E purports to be a copy of the letter dated January 22, 2017.

78. The January 22, 2017 letter stated that Bioepis continued to regard its May 26, 2016, letter as constituting effective notice of commercial marketing. Bioepis acknowledged that under controlling law its early "notice" was ineffective but stated that the effectiveness might change depending on the outcome of the U.S. Supreme Court's forthcoming decision in *Amgen v. Sandoz* (No. 15-1159). Bioepis concluded by stating that it would "assert its rights in accordance

with the decision of the U.S. Supreme Court and will provide Janssen with an additional commercial marketing notice at the time of FDA licensure if necessary."

ANSWER: Defendant admits sending to Janssen a letter dated January 22, 2017, admits that its January 22 letter referred to Bioepis' notice of commercial marketing in its May 26, 2016 letter, and admits that its January 22 letter stated that Bioepis would assert its rights in accordance with the decision of the U.S. Supreme Court in *Sandoz Inc. v. Amgen Inc.*, but Defendant otherwise denies the allegations of paragraph 78. Defendant denies the allegations of paragraph 78 as a misstatement of applicable law. Defendant denies that its May 26, 2016 notice was either "early" or "ineffective" as a matter of law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017).

79. On April 21, 2017, upon FDA's approval of its biosimilar product, Bioepis sent an additional letter, attached as Exhibit F.

ANSWER: Defendant admits that after the FDA approval of Bioepis's BLA No. 761054, Bioepis sent Janssen a letter dated April 21, 2017. Defendant admits that Exhibit F purports to be a copy of the letter dated April 21, 2017.

80. In the April 21, 2017 letter, Bioepis stated again that the May 26, 2016 letter was an effective notice of commercial marketing and that it is "authorized by the FDA to commercially market" its biosimilar and it would "commercially market" the biosimilar "as soon as possible under applicable law."

ANSWER: Defendant admits sending to Janssen a letter dated April 21, 2017. Defendant admits that its April 21, 2017 letter (i) referred Plaintiff to Bioepis' letter dated May 26, 2016 providing Bioepis' commercial marketing notice to Plaintiff, and (ii) stated that Bioepis

"will commercially market the biological product that is the subject of BLA No. 761054 as soon as possible under applicable law." Defendant otherwise denies the allegations of paragraph 80.

81. In accordance with controlling law, Bioepis stated that the April 21, 2017 letter should also be treated as a notice of commercial marketing, in the event that the May 26, 2016, letter is "held to be void or otherwise ineffective."

ANSWER: Defendant admits sending to Janssen a letter dated April 21, 2017. Defendant admits that the April 21 letter stated, in part, that in the event Bioepis' May 26, 2016 commercial marketing notice was held to be void or otherwise ineffective that Bioepis "hereby notifies Janssen Biotech, Inc. in accordance with 42 U.S.C. § 262(1)(8)(A) that Bioepis will commence commercial marketing of the biological product that is the subject of BLA No. 761054 as soon as possible but no earlier than 180 days from the receipt by Janssen Biotech, Inc. of Bioepis's commercial marketing notice." This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 81 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 81.

82. As of its letter of April 21, 2017, Bioepis has refused to participate in any of the BPCIA's patent dispute resolution procedures, and Bioepis has made it impossible for Janssen to assess which of Janssen's patents are infringed.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 82 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664

(2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 82.

83. Given Bioepis's refusal to comply with the provisions of the BPCIA so as to allow Janssen to assess infringement of its patents and protect its intellectual property rights, Janssen has filed this Complaint to protect its interests and to enforce its patents and the statutory provisions which Bioepis seeks to bypass.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 83 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 83.

Bioepis's Premature Notice of Commercial Marketing

84. On May 26, 2016, in the same letter in which Bioepis refused to provide its aBLA and manufacturing information, Bioepis stated (prematurely) that it was providing a notice of commercial marketing, purportedly pursuant to 42 U.S.C. § 262(*l*)(8)(A). Bioepis asserted that it would begin commercial marketing of its proposed biosimilar product "as soon as possible" after the FDA's approval and as early as "180 days from the receipt of this notice," i.e., as early as November 22, 2016.

ANSWER: Defendant admits that its May 26, 2016 letter states that "Bioepis hereby provides notice to Janssen Biotech, Inc. in accordance with 42 U.S.C. § 262(1)(8)(A) that Bioepis will commence commercial marketing of the biological product that is the subject of BLA No. 761054 as soon as possible under applicable law after the FDA's approval to do so but no earlier than 180 days from receipt of this notice by Janssen Biotech, Inc." This paragraph

contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 84 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 84.

85. The BPCIA includes a clear condition precedent to providing a notice of commercial marketing. The statutorily required notice is "of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The grant of a license under subsection (k) is a statutory prerequisite to providing a notice of commercial marketing.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 85 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 85.

86. As Bioepis is aware, this was precisely the holding of the Federal Circuit in *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015) and *Amgen, Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016). In *Amgen v. Sandoz* the Federal Circuit held that a biosimilar application "may only give effective notice of commercial marketing after the FDA has licensed its product." *Sandoz*, 794 F.3d at 1357. The Federal Circuit reaffirmed that holding in *Amgen v. Apotex*, explaining that "the notice starting the 180-day clock must follow, not precede, the licensure." *Apotex*, 827 F.3d at 1056.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. The Federal Circuit Court of Appeals decisions cited in paragraph 86 are not applicable law. The Federal Circuit Court of Appeals decisions cited in paragraph 86 were reversed by the U.S. Supreme Court. Defendant denies the allegations of paragraph 86 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 86.

87. Bioepis had not, at the time of its May 26, 2016 letter, received a license to market its proposed biosimilar product under subsection (k). As a result, Bioepis's proposed product was not a "biological product licensed under subsection (k)" and could not be the subject of a valid notice of commercial marketing pursuant to the BPCIA.

ANSWER: Defendant admits that as of its May 26, 2016 letter, Bioepis had not received a license to market its proposed biosimilar product. This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 87 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 87.

88. The purpose of the notice of commercial marketing provision is to provide the parties and the Court with sufficient time (180 days) to resolve any disputes that need to be resolved before commercial launch of a biosimilar product. If Bioepis is allowed to proceed based on its invalid notice of commercial marketing, the 180-day period would have already run,

during a time when the precise nature of the dispute between the parties, and even the need for litigation on certain patents, had not yet crystallized.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 88 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 88.

89. On January 12, 2017, Janssen asked Bioepis to withdraw its premature notice of commercial marketing.

ANSWER: Defendant admits receiving a letter from Janssen dated January 12, 2017, but otherwise denies the allegations of paragraph 89.

90. On January 22, 2017, Bioepis refused to withdraw the notice of commercial marketing, although it confirmed that it would comply with applicable law.

ANSWER: Defendant admits sending to Janssen a letter dated January 22, 2017, admits that the January 22 letter states that Bioepis "will not commence commercial marketing of the product that is the subject of the referenced BLA before the expiration date of 180 days from the receipt by Janssen of a commercial marketing notice from Bioepis that is proper under applicable law," but otherwise denies the allegations of paragraph 90.

91. On April 21, 2017, Bioepis provided Janssen with a post-licensure notice of commercial marketing but said it would rely on its prior notice if the law changes.

ANSWER: Defendant admits sending to Janssen a letter dated April 21, 2017. Defendant admits that (i) its April 21, 2017 letter informed Plaintiff of the FDA approval of Bioepis' drug product under BLA No. 761054, (ii) referred Plaintiff to Bioepis' commercial

marketing notice of May 26, 2016, and (iii) stated that, in the event Bioepis' May 26, 2016 commercial marketing notice was held to be void or otherwise ineffective, Bioepis "hereby notifies Janssen Biotech, Inc. in accordance with 42 U.S.C. § 262(1)(8)(A) that Bioepis will commence commercial marketing of the biological product that is the subject of BLA No. 761054 as soon as possible but no earlier than 180 days from the receipt by Janssen Biotech, Inc. of Bioepis's commercial marketing notice." Defendant otherwise denies the allegations of paragraph 91.

COUNT 1: VIOLATION OF MANDATORY PROCEDURES UNDER 42 U.S.C. § 262(*1*)(2)

92. Janssen incorporates by reference paragraphs 1-91 as if fully set forth herein.

ANSWER: Defendant restates and incorporates each of its responses to paragraphs 1-91 as if fully set forth herein.

93. This claim arises under the BPCIA, 42 U.S.C. § 262(*l*)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202.

ANSWER: Defendant denies that Plaintiff has stated a justiciable claim to enforce the alleged patent dispute resolutions under the BPCIA, 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202. Defendant denies that the BPCIA provides for a private right of action to enforce the patent dispute resolution provisions set forth in 42 U.S.C. § 262(*l*). Defendant denies the allegations of paragraph 93 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). Defendant denies that Plaintiff is entitled to any relief in this action. Defendant denies the remaining allegations of paragraph 93.

94. The BPCIA, 42 U.S.C. § 262(*l*)(2), provides procedures to resolve patent disputes related to the filing of an aBLA under 42 U.S.C. § 262(k).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 94 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 94.

95. Bioepis has failed to comply with the requirements of the BPCIA. Bioepis's failure to follow the procedures set forth in the BPCIA has injured Janssen by depriving it of the procedural protections of the statute and by subjecting it to the burden of unnecessary litigation.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 95 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 95.

96. Contrary to 42 U.S.C. § 262(*l*)(2)(A), Bioepis did not provide Janssen with a copy of the aBLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." Indeed, Bioepis expressly refused to do so. By refusing to provide the information set forth under the BPCIA, Bioepis has made it impossible for Janssen to assess infringement of its patents. Bioepis has benefited from the BPCIA's regulatory pathway and Janssen's years of research and development while withholding information critical for Janssen to protect its patent rights.

ANSWER: Defendant admits that Bioepis did not provide Janssen with a copy of Bioepis' BLA or other process information. This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the

allegations of paragraph 96 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137, S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 96.

97. Bioepis's failure to follow the BPCIA's procedures, individually and collectively, has caused and will cause Janssen injury, including irreparable harm for which Janssen has no adequate remedy at law, and will continue unless the statutory requirements are declared and enforced by this Court.

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 97 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 97.

98. Under current law, the Federal Circuit has not interpreted 42 U.S.C. § 262(*l*)(2)(A) to be mandatory. *See Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies that the decision of the U.S. Court of Appeals for the Federal Circuit cited in paragraph 98 is current law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 98.

99. However, on January 13, 2017, the Supreme Court granted *certiorari* on this precise issue in *Amgen, Inc. v. Sandoz, Inc.* (U.S. Jan. 13, 2017) (No. 15-1195).

ANSWER: Defendant admits that the U.S. Supreme Court granted *certiorari* in *Amgen, Inc. v. Sandoz, Inc.* (U.S. Jan. 13, 2017) (No. 15-1195). Defendant denies all characterizations of the law, including issues presented to the U.S. Supreme Court for review, statutes and pertinent case law, and denies the allegations, of paragraph 99.

100. As such, Janssen includes this Count 1 as the Supreme Court may hold that biosimilar makers that make use of the BPCIA's regulatory procedures also must follow its patent dispute resolution procedures, the first step of which is 42 U.S.C. § 262(*l*)(2)(A).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 100 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 100.

COUNT 2: VIOLATION OF MANDATORY PROCEDURES UNDER 42 U.S.C. § 262(*l*)

101. Janssen incorporates by reference paragraphs 1-100 as if fully set forth herein.

ANSWER: Defendant restates and incorporates each of its responses to paragraphs 1-100 as if fully set forth herein.

102. The BPCIA provides that a biosimilar applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A).

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. Defendant denies the allegations of paragraph 102

as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 102.

103. This requirement has been held by the Federal Circuit to be mandatory. *See Amgen, Inc. v. Apotex Inc.*, 827 F.3d 1052, 1056 (Fed. Cir. 2016), *cert. denied*, 85 U.S.L.W. 3287 (U.S. Dec. 12, 2016) (No. 16-332) ("[T]he notice starting the 180-day clock must follow, not precede, the licensure."); *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015) ("[A] subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product.").

ANSWER: This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. The decisions of the U.S. Court of Appeals for the Federal Circuit cited in paragraph 103 are not current law. The Federal Circuit decisions were reversed by the U.S. Supreme Court in *Sandoz Inc. v. Amgen Inc.*, and are not applicable law. Defendant denies the allegations of paragraph 103 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 103.

104. Bioepis has provided two letters purportedly providing notice of commercial marketing, the first of which is not effective. Bioepis has refused to withdraw the ineffective notice but states that it will comply with applicable law.

ANSWER: Defendant admits that Bioepis has provided two letters providing notice of commercial marketing. Defendant denies that its first letter, dated May 26, 2016, was not an effective notice of commercial marketing. Defendant denies the allegations of paragraph 104 as

a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). The remaining allegations of this paragraph contain legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 104.

105. If Bioepis were to rely on an ineffective notice or not comply with the law, its violation of the notice of commercial marketing provision would cause Janssen injury, including irreparable harm for which Janssen has no adequate remedy at law, and will continue unless the statutory requirement is declared and enforced by this Court.

ANSWER: Defendant denies that it has or will rely on an ineffective notice of commercial marketing or that it will not comply with the law. Defendant denies the allegations of paragraph 105 as a misstatement of applicable law. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017). This paragraph contains legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 105.

COUNT 3: INFRINGEMENT OF THE '083 PATENT

106. Janssen incorporates by reference paragraphs 1-105 as if fully set forth herein.

ANSWER: Defendant restates and incorporates each of its responses to paragraphs 1-105 as if fully set forth herein.

107. On information and belief, Bioepis has been aware of the '083 patent since a time before Bioepis filed its aBLA.

ANSWER: Defendant admits that Bioepis has been aware of the '083 patent since a time before Bioepis filed its BLA.

108. Bioepis's submission of its aBLA was an act of infringement of the '083 patent under 35 U.S.C. § 271(e)(2)(C)(ii), literally or under the doctrine of equivalents.

ANSWER: Bioepis denies that the manufacture, use, sale, offer for sale or importation of its biosimilar drug product in the United States will infringe any claim of the '083 patent literally, or under the doctrine of equivalents. The remaining allegations of this paragraph contain legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law. Defendant denies the remaining allegations of paragraph 108.

109. Upon information and belief, Bioepis's infringement of the '083 patent would be willful and would make this case exceptional entitling Janssen to attorneys' fees.

ANSWER: Defendant denies the allegations of paragraph 109.

110. Unless Bioepis is enjoined from infringing the '083 patent, Janssen will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Defendant denies the allegations of paragraph 110.

COUNT 4: INFRINGEMENT OF THE '056 PATENT

111. Janssen incorporates by reference paragraphs 1-110 as if fully set forth herein.

ANSWER: Defendant restates and incorporates each of its responses to paragraphs 1-110 as if fully set forth herein.

112. On information and belief, Bioepis has been aware of the '056 patent since a time before Bioepis filed its aBLA.

ANSWER: Defendant admits that Bioepis has been aware of the '056 patent since a time before Bioepis filed its BLA.

113. Bioepis's submission of its aBLA was an act of infringement of the '056 patent under 35 U.S.C. § 271(e)(2)(C)(ii), literally or under the doctrine of equivalents.

ANSWER: Bioepis denies that the manufacture, use, sale, offer for sale or importation of its biosimilar drug product in the United States will infringe the '056 patent, literally or under the doctrine of equivalents. The remaining allegations of this paragraph contain legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law. Defendant denies the remaining allegations of paragraph 113.

114. Upon information and belief, Bioepis's infringement of the '056 patent would be willful and would make this case exceptional entitling Janssen to attorneys' fees.

ANSWER: Defendant denies the allegations of paragraph 114.

115. Unless Bioepis is enjoined from infringing the '056 patent, Janssen will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Defendant denies the allegations of paragraph 115.

COUNT 5: INFRINGEMENT OF THE '600 PATENT

116. Janssen incorporates by reference paragraphs 1-115 as if fully set forth herein.

ANSWER: Defendant restates and incorporates each of its responses to paragraphs 1-115 as if fully set forth herein.

117. On information and belief, Bioepis has been aware of the '600 patent since a time before Bioepis filed its aBLA.

ANSWER: Defendant admits that Bioepis has been aware of the '600 patent since a time before Bioepis filed its BLA.

118. Bioepis's submission of its aBLA was an act of infringement of the '600 patent under 35 U.S.C. § 271(e)(2)(C)(ii), literally or under the doctrine of equivalents.

ANSWER: Bioepis denies that the manufacture, use, sale, offer sale or importation of its biosimilar drug product in the United States will infringe the '600 patent, literally or under the doctrine of equivalents. The remaining allegations of this paragraph contain legal contentions, legal argument, and legal conclusions to which no answer is required. To the extent an answer is required, Defendant denies all characterizations of the law, including statutes and pertinent case law, and denies the allegations, of paragraph 118.

119. Upon information and belief, Bioepis's infringement of the '600 patent would be willful and would make this case exceptional entitling Janssen to attorneys' fees.

ANSWER: Defendant denies the allegations of paragraph 119.

120. Unless Bioepis is enjoined from infringing the '600 patent, Janssen will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Defendant denies the allegations of paragraph 120.

PRAYER FOR RELIEF

Defendant denies all allegations not specifically admitted herein, and further denies that Plaintiff is entitled to the judgment and relief requested in the Prayer for Relief set forth in the Complaint or to any other relief.

AFFIRMATIVE AND SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 120 of the Complaint, Defendant alleges the following affirmative defenses. Defendant expressly

reserves the right to allege additional defenses as they become known through the course of discovery. Defendant does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiff bears the burden of proof.

First Defense

The Court lacks jurisdiction over Count 1; the BPCIA does not confer a private right of action to enforce allegations of non-compliance with the statutory requirements, and there is no case or controversy to enforce the remedy in 42 U.S.C. § 262(*l*)(9)(C). Plaintiff has not stated a justiciable claim for violation of 42 U.S.C. § 262(*l*). *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017).

Second Defense

Defendant's May 26, 2016 notice of commercial marketing complies with 42 U.S.C. § 262(*l*)(8)(A). *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. __, 137 S. Ct. 1664 (2017).

Third Defense

The manufacture, use, sale, offer for sale, or importation of the biosimilar infliximab product pursuant to Bioepis's BLA will not infringe, directly or indirectly, any claim of the '083 patent, '056 patent, or '600 patent, either literally or under the doctrine of equivalents. Further, any claim for infringement is barred by the doctrine of prosecution history estoppel and/or Defendant's practicing of the prior art.

Fourth Defense

The claims of the '083 patent, '056 patent, and '600 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability, including obviousness-type double patenting.

Fifth Defense

Plaintiff's complaint fails to state a claim upon which relief may be granted.

Sixth Defense

Defendant's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 271(e)(4) or 35 U.S.C. § 285.

Seventh Defense

Defendant has not willfully infringed any claim of the '083 patent, '056 patent, or '600 patent.

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal, as Plaintiff has not begun producing discovery to Defendant, and Defendant has not yet had the opportunity to pursue relevant third-party discovery.

Ninth Defense

Janssen Biotech is not the owner of the entire right, title and interest to any of the '083, '056, and '600 patents and, as such, does not have the legal right to sue for infringement of any one or more of such patents.

REQUEST FOR RELIEF

WHEREFORE, Defendant Samsung Bioepis, Co., Ltd. prays that this Court enter judgment against Plaintiff Janssen Biotech, Inc. as follows:

(a) declaring that the manufacture, sale, offer for sale, use or importation of the infliximab biosimilar drug product described in Bioepis' BLA does not and will not infringe, either literally or under the doctrine of equivalents, directly or indirectly, either by inducement or contributorily, any claim of the '083 patent;

(b) declaring that the claims of the ’083 patent are invalid and/or unenforceable against Defendant;

(c) declaring that the manufacture, sale, offer for sale, use or importation of the infliximab biosimilar drug product described in Bioepis’ BLA does not and will not infringe, either literally or under the doctrine of equivalents, directly or indirectly, either by inducement or contributorily, any claim of the ‘056 patent;

(d) declaring that the claims of the ’056 patent are invalid and/or unenforceable against Defendant;

(e) declaring that the manufacture, sale, offer for sale, use or importation of the infliximab biosimilar drug product described in Bioepis’ BLA does not and will not infringe, either literally or under the doctrine of equivalents, directly or indirectly, either by inducement or contributorily, any claim of the ‘600 patent;

(f) declaring that the claims of the ’600 patent are invalid and/or unenforceable against Defendant;

(g) ordering that Plaintiff’s complaint be dismissed with prejudice and judgment entered in favor of Defendant;

(h) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Defendant attorney fees, costs and expenses in this action; and

(i) awarding Defendant any further and additional relief as the Court deems just and proper.

Date: July 21, 2017

/s/ Michael E. Patunas

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